115TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
115–724

OVERDOSE PREVENTION AND PATIENT SAFETY ACT

JUNE 12, 2018.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WALDEN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 5795]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5795) to amend the Public Health Service Act to protect the confidentiality of substance use disorder patient records, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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79–006

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Overdose Prevention and Patient Safety Act".

SEC. 2. CONFIDENTIALITY AND DISCLOSURE OF RECORDS RELATING TO SUBSTANCE USE DISORDER.

(a) CONFORMING CHANGES RELATING TO SUBSTANCE USE DISORDER.—Subsections (a) and (h) of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) are each amended by striking "substance abuse" and inserting "substance use disorder".

(b) DISCLOSURES TO COVERED ENTITIES CONSISTENT WITH HIPAA.—Paragraph (2) of section 543(b) of the Public Health Service Act (42 U.S.C. 290dd–2(b)) is amended by adding at the end the following:

"(D) To a covered entity or to a program or activity described in subsection (a), for the purposes of treatment, payment, and health care operations, so long as such disclosure is made in accordance with HIPAA privacy regulation. Any redisclosure of information so disclosed may only be made in accordance with this section.".

(c) DISCLOSURES OF DE-IDENTIFIED HEALTH INFORMATION TO PUBLIC HEALTH AUTHORITIES.—Paragraph (2) of section 543(b) of the Public Health Service Act (42 U.S.C. 290dd–2(b)), as amended by subsection (b), is further amended by adding at the end the following:

"(E) To a public health authority, so long as such content does not include any individually identifiable health information and meets the standards established in section 164.514 of title 45, Code of Federal Regulations (or successor regulations) for creating de-identified information.".

(d) DEFINITIONS.—Subsection (b) of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following:

"(3) DEFINITIONS.—For purposes of this subsection:

"(A) COVERED ENTITY.—The term 'covered entity' has the meaning given such term for purposes of HIPAA privacy regulation.

"(B) HEALTH CARE OPERATIONS.—The term 'health care operations' has the meaning given such term for purposes of HIPAA privacy regulation.

"(C) HIPAA PRIVACY REGULATION.—The term 'HIPAA privacy regulation' has the meaning given such term under section 1180(b)(3) of the Social Security Act.

"(D) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term 'individually identifiable health information' has the meaning given such term for purposes of HIPAA privacy regulation.

"(E) PAYMENT.—The term 'payment' has the meaning given such term for purposes of HIPAA privacy regulation.

"(F) PUBLIC HEALTH AUTHORITY.—The term 'public health authority' has the meaning given such term for purposes of HIPAA privacy regulation.

"(G) TREATMENT.—The term 'treatment' has the meaning given such term for purposes of HIPAA privacy regulation.".

(e) USE OF RECORDS IN CRIMINAL, CIVIL, OR ADMINISTRATIVE INVESTIGATIONS, ACTIONS, OR PROCEEDINGS.—Subsection (c) of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) is amended to read as follows:

"(c) USE OF RECORDS IN CRIMINAL, CIVIL, OR ADMINISTRATIVE CONTEXTS.—Except as otherwise authorized by a court order under subsection (b)(2)(C) or by the consent of the patient, a record referred to in subsection (a) may not—

"(1) be entered into evidence in any criminal prosecution or civil action before a Federal or State court;

"(2) form part of the record for decision or otherwise be taken into account in any proceeding before a Federal agency;

"(3) be used by any Federal, State, or local agency for a law enforcement purpose or to conduct any law enforcement investigation of a patient; or

"(4) be used in any application for a warrant.".

(f) PENALTIES.—Subsection (f) of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) is amended to read as follows:

"(f) PENALTIES.—The provisions of sections 1176 and 1177 of the Social Security Act shall apply to a violation of this section to the extent and in the same manner as such provisions apply to a violation of part C of title XI of such Act. In applying the previous sentence—

"(1) the reference to 'this subsection' in subsection (a)(2) of such section 1176 shall be treated as a reference to 'this subsection (including as applied pursuant to section 543(f) of the Public Health Service Act)'; and

"(2) in subsection (b) of such section 1176—

"(A) each reference to 'a penalty imposed under subsection (a)' shall be treated as a reference to 'a penalty imposed under subsection (a) (including as applied pursuant to section 543(f) of the Public Health Service Act)'; and

"(B) each reference to 'no damages obtained under subsection (d)' shall be treated as a reference to 'no damages obtained under subsection (d) (including as applied pursuant to section 543(f) of the Public Health Service Act)'.".

(g) ANTIDISCRIMINATION.—Section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following:

"(i) ANTIDISCRIMINATION.—

"(1) IN GENERAL.—No entity shall discriminate against an individual on the basis of information received by such entity pursuant to a disclosure made under subsection (b) in—

"(A) admission or treatment for health care;

"(B) hiring or terms of employment;

"(C) the sale or rental of housing; or

"(D) access to Federal, State, or local courts.

"(2) RECIPIENTS OF FEDERAL FUNDS.—No recipient of Federal funds shall discriminate against an individual on the basis of information received by such recipient pursuant to a disclosure made under subsection (b) in affording access to the services provided with such funds.".

(h) NOTIFICATION IN CASE OF BREACH.—Section 543 of the Public Health Service Act (42 U.S.C. 290dd–2), as amended by subsection (g), is further amended by adding at the end the following:

"(j) NOTIFICATION IN CASE OF BREACH.—

"(1) APPLICATION OF HITECH NOTIFICATION OF BREACH PROVISIONS.—The provisions of section 13402 of the HITECH Act (42 U.S.C. 17932) shall apply to a program or activity described in subsection (a), in case of a breach of records described in subsection (a), to the same extent and in the same manner as such provisions apply to a covered entity in the case of a breach of unsecured protected health information.

"(2) DEFINITIONS.—In this subsection, the terms 'covered entity' and 'unsecured protected health information' have the meanings given to such terms for purposes of such section 13402.".

(i) SENSE OF CONGRESS.—It is the sense of the Congress that any person treating a patient through a program or activity with respect to which the confidentiality requirements of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) apply should access the applicable State-based prescription drug monitoring program as a precaution against substance use disorder.

(j) REGULATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with appropriate Federal agencies, shall make such revisions to regulations as may be necessary for implementing and enforcing the amendments made by this section, such that such amendments shall apply with respect to uses and disclosures of information occurring on or after the date that is 12 months after the date of enactment of this Act.

(2) EASILY UNDERSTANDABLE NOTICE OF PRIVACY PRACTICES.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate experts, shall update section 164.520 of title 45, Code of Federal Regulations, so that covered entities provide notice, written in plain language, of privacy practices regarding patient records referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)), including—

(A) a statement of the patient's rights, including self-pay patients, with respect to protected health information and a brief description of how the individual may exercise these rights (as required by paragraph (b)(1)(iv) of such section 164.520); and

(B) a description of each purpose for which the covered entity is permitted or required to use or disclose protected health information without the patient's written authorization (as required by paragraph (b)(2) of such section 164.520).

(k) DEVELOPMENT AND DISSEMINATION OF MODEL TRAINING PROGRAMS FOR SUBSTANCE USE DISORDER PATIENT RECORDS.—

(1) INITIAL PROGRAMS AND MATERIALS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), in consultation with appropriate experts, shall identify the following model programs and materials (or if no such programs or materials exist, recognize private or public entities to develop and disseminate such programs and materials):

(A) Model programs and materials for training health care providers (including physicians, emergency medical personnel, psychiatrists, psychologists, counselors, therapists, nurse practitioners, physician assistants, behavioral health facilities and clinics, care managers, and hospitals, including individuals such as general counsels or regulatory compliance staff who are responsible for establishing provider privacy policies) concerning the permitted uses and disclosures, consistent with the standards and regulations governing the privacy and security of substance use disorder patient records promulgated by the Secretary under section 543 of the Public Health Service Act (42 U.S.C. 290dd–2), as amended by this section, for the confidentiality of patient records.

(B) Model programs and materials for training patients and their families regarding their rights to protect and obtain information under the standards and regulations described in subparagraph (A).

(2) REQUIREMENTS.—The model programs and materials described in subparagraphs (A) and (B) of paragraph (1) shall address circumstances under which disclosure of substance use disorder patient records is needed to—

(A) facilitate communication between substance use disorder treatment providers and other health care providers to promote and provide the best possible integrated care;

(B) avoid inappropriate prescribing that can lead to dangerous drug interactions, overdose, or relapse; and

(C) notify and involve families and caregivers when individuals experience an overdose.

(3) PERIODIC UPDATES.—The Secretary shall—

(A) periodically review and update the model programs and materials identified or developed under paragraph (1); and

(B) disseminate such updated programs and materials to the individuals described in paragraph (1)(A).

(4) INPUT OF CERTAIN ENTITIES.—In identifying, reviewing, or updating the model programs and materials under this subsection, the Secretary shall solicit the input of relevant stakeholders.

(l) RULES OF CONSTRUCTION.—Nothing in this Act or the amendments made by this Act shall be construed to limit—

(1) a patient's right, as described in section 164.522 of title 45, Code of Federal Regulations, or any successor regulation, to request a restriction on the use or disclosure of a record referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)) for purposes of treatment, payment, or health care operations; or

(2) a covered entity's choice, as described in section 164.506 of title 45, Code of Federal Regulations, or any successor regulation, to obtain the consent of the individual to use or disclose a record referred to in such section 543(a) to carry out treatment, payment, or health care operation.

(m) SENSE OF CONGRESS.—It is the sense of the Congress that—

(1) patients have the right to request a restriction on the use or disclosure of a record referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)) for treatment, payment, or health care operations; and

(2) covered entities should make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding such use or disclosure.

PURPOSE AND SUMMARY

H.R. 5795, the Overdose Prevention and Patient Safety Act, was introduced on May 15, 2018, by Rep. Earl Blumenauer (D–OR) and Rep. Markwayne Mullin (R–OK). The bill permits substance use disorder (SUD) treatment records to be shared between covered entities in accordance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, for the purposes of treatment, payment, and healthcare operations. In order to protect individuals seeking and receiving SUD treatment, the bill enhances the protections on the disclosure of SUD treatment records to non-covered entities by, except for authorization by court order or by consent of the patient, prohibiting the use of these records in any criminal, civil, or administrative investigations, actions, or proceedings. The legislation increases the penalties in the event of unlawful disclo-

sure of SUD treatment records and establishes breach notification requirements in accordance with the Health Information Technology for Economic and Clinical Health (HITECH) Act. Finally, in the case of any entity legally or illegally in receipt of SUD treatment information, H.R. 5795 prohibits the entity from discriminating against an individual in admission or treatment for healthcare; hiring or terms of employment; the sale or rental of housing; and access to Federal, State, or local courts. All recipients of Federal funds are also prohibited from using SUD treatment records as the basis of discriminating against an individual.

BACKGROUND AND NEED FOR LEGISLATION

Federal confidentiality law and regulations (42 C.F.R. Part 2, or Part 2) were enacted in the 1970s after Congress recognized that the fear of prosecution and the stigma associated with SUD and fear of prosecution decreased the likelihood patients would enter into treatment.[1] [2]

Part 2 regulations impose more restrictions on the disclosure of substance use disorder treatment records than most other Federal and State health privacy laws, including the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) under HIPAA.[3] The HIPAA Privacy Rule sets national standards for the protection of health information and applies broadly to identifiable health information that is created or received by payers and providers of health care. It also applies to the business associates of these covered entities that provide specific services (e.g., claims processing, data management) for covered entities to help them operate and meet their responsibilities to patients. Under the HIPAA Privacy Rule, health information may be used or disclosed by covered entities (health providers, payers, and clearinghouses) for the purposes of treatment, payment, and other healthcare operations—including case management, care coordination, and outcomes evaluation. The Privacy Rule also outlines other various circumstances under which covered entities may use or disclose health information.

Compared to the HIPAA Privacy Rule, Part 2 is much narrower in scope and permits fewer uses and disclosures of patient information without express written consent. Under Part 2, any information regarding:

> the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States

is confidential.[4] This information may be disclosed only with the patient's written consent, pursuant to a court order, or if the disclo-

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[1] Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970, P.L. 91–61

[2] Drug Abuse Office and Treatment Act of 1972, P.L. 92–255

[3] Health Insurance Portability and Accountability Act of 1996, P.L. 104–191

[4] 42 U.S.C. § 290dd–2. Confidentiality of records.

sure falls within one of a few statutory exceptions. The regulations apply to holders, recipients, and seekers of this information.

Part 2 also places very strict limitations on the redisclosure of such records. Anyone who receives such information from a SUD treatment program may not redisclose it without consent or as otherwise authorized by the regulations and may not use it except for certain purposes. Part 2 technically applies only to Federally assisted organizations and individual practitioners that specialize in providing SUD treatment or referral for treatment. However, with few exceptions, most of the nation's alcohol and drug treatment programs receive Federal funding.

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), individuals with mental and substance abuse disorders die decades earlier than the average person—mostly from untreated chronic illnesses that are aggravated by poor health habits. SAMHSA has made clear that integrating mental health, substance abuse, and primary care services produces the best outcomes and proves the most effective approach to caring for people with multiple healthcare needs.[5] However, Part 2 serves as a barrier for initiatives that promote enhanced access and care continuity, such as health information exchanges, integrated care networks, health homes, and accountable care organizations. In addition, Part 2 is not uniformly applied to all providers treating patients with SUD. Patient information maintained in connection with the Veterans' Health Administration is not subject to Part 2. For-profit treatment providers that do not receive any Federal assistance do not have to comply with Part 2. Buprenorphine prescribers may or may not be subject to Part 2 depending on whether the provider considers itself as an entity that specifically provides SUD diagnosis, treatment, or referral for treatment.[6]

Because of disparities between HIPAA and Part 2, the health provider community has become increasingly frustrated with the restrictions that Part 2 places on their ability to improve the coordination and quality of care by sharing SUD treatment records. Access to a patient's entire medical record, including addiction records, ensures that health providers and organizations have all the information necessary for safe, effective, high quality treatment, and care coordination that addresses all of a patient's unique health needs. Failure to integrate services and supports can lead to risks and dangers to individual patients, such as dangerous drug interactions[7] and problems related to medication adherence. Obtaining multiple consents from a patient can often be challenging and creates barriers to whole person, integrated approaches to care.

SAMHSA revised the Part 2 regulations in 1987 and in 2017. The most recently released final regulations and supplemental notice of proposed rulemaking were an attempt to align Part 2 with the HIPAA Privacy Rule to the extent feasible under current law

[5] SAMHSA–HRSA Center for Integrated Health Solutions. "What is integrated care?" 2016. Available at http://www.integration.samhsa.gov/resource/what-is-integrated-care.

[6] American Psychiatric Association. "Final Rule: 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records." 2017. Available at https://www.psychiatry.org/psychiatrists/practice/practice-management/hipaa/42-cfr-part-2.

[7] McCance-Katz EF, Sullivan L, Nallani S, Drug Interactions of Clinical Importance among the Opioids, Methadone and Buprenorphine, and other Frequently Prescribed Medications: A Review. *Am J Addict.* 19: 4–16 (2010). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3334287/.

by making it easier to share these records within accountable care organizations and health information exchanges. Under the newly-created general designation process promulgated under final regulations, a patient may consent to share his or her information with an intermediary, such as a health information exchange (HIE), accountable care organization (ACO), or other integrated care setting.[8] However, a recipient of this information within an HIE or ACO with a treating provider relationship is prohibited from re-disclosing that information to another provider in the same HIE or ACO without additional patient consent, rendering the process unworkable in practice.[9] SAMHSA has stated that the agency is encouraged that Congress is reviewing the issue and has made clear that any further changes to Part 2 would require a change to the underlying statute.[10]

COMMITTEE ACTION

On March 21 and 22, 2108, the Subcommittee on Health held a hearing on H.R. 3545, Overdose Prevention and Patient Safety Act, which was similar to H.R. 5795. The hearing was entitled "Combatting the Opioid Crisis: Prevention and Public Health Solutions." The Subcommittee received testimony from:

- Scott Gottlieb, MD, Commissioner, Food and Drug Administration;
- Anne Schuchat, MD (RADM, USPHS), Acting Director, Centers for Disease Control and Prevention;
- Christopher M. Jones, PharmD, MPH, Director, National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration;
- Sue Thau, Public Policy Consultant, Community Anti-Drug Coalitions of America;
- Cartier Esham, Executive Vice President, Emerging Companies, Biotechnology Innovation Organization;
- Jeffrey Francer, Senior Vice President and General Counsel, Association for Accessible Medicines;
- John W. Holaday, PhD, Chairman and Co-Founder, DisposeRx;
- Eric C. Strain, MD, Director, Center for Substance Abuse Treatment and Research, Johns Hopkins University School of Medicine;
- Kenneth J. Martz, PsyD MBA, Special Projects Consultant, Gaudenzia, Inc.;
- Brad Bauer, Senior Vice President of New Business Development and Customer Relationship Management, Appriss Health;
- William Banner, MD, PhD, Medical Director, Oklahoma Center for Poison and Drug Information; Board President, American Association of Poison Control Centers;

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[8] 42 CFR § 2.31(a)(4)(iii)(B). Consent requirements.

[9] United States Congress. House Energy and Commerce Committee, Subcommittee on Health. *Improving the Coordination and Quality of Substance Use Disorder Treatment.* May 8, 2018. 115th Congress, 2nd session. (2018) (statement of Gerald (Jud) E. DeLoss, Greensfelder Hemker & Gale P.C.). Available at https://docs.house.gov/meetings/IF/IF14/20180508/108271/HHRG-115-IF14-Wstate-DeLossG–20180508.pdf.

[10] McKance-Katz, Elinore F. (Substance Abuse and Mental Health Services Administration) Letter to the Honorable Markwayne Mullin. March 19, 2018. Available at https://docs.house.gov/meetings/IF/IF14/20180321/108049/HHRG-115-IF14-20180321-SD100.pdf.

- Michael E. Kilkenny, MD, MS, Physician Director, Cabell-Huntington Health Department of West Virginia;
- Jessica Hulsey Nickel, Founder, President and CEO, Addiction Policy Forum;
- Ryan Hampton, Recovery Advocate, Facing Addiction;
- Carlene Deal-Smith, Peer Support Specialist, Presbyterian Medical Services;
- Mark Rosenberg, DO, MBA, FACEP, FAAHPM, Chairman of Emergency Medicine and Chief Innovation Officer, St. Joseph's Healthcare System; Board of Directors, American College of Emergency Physicians;
- Stacy Bohlen, CEO, National Indian Health Board; and
- Alexis Horan, Vice President of Government Relations, Clean Slate Centers.

In addition, on May 8, 2018, the Subcommittee on Health held a hearing on a discussion draft entitled "Overdose Prevention and Patient Safety Act," which was similar to H.R. 5795. The hearing was entitled "Improving the Coordination and Quality of Substance Use Disorder Treatment." The Subcommittee received testimony from:

- Earl Blumenauer (D–OR), Member, U.S. House of Representatives;
- Gerald (Jud) E. DeLoss, Officer, Greensfelder, Hemker and Gale, P.C;
- Jeremiah Gardner, Manager of Public Affairs and Advocacy, Hazelden Betty Ford Foundation;
- Dustin McKee, Director of Policy, National Alliance on Mental Illness of Ohio;
- H. Westley Clark, M.D., J.D., M.P.H., Dean's Executive Professor, Public Health Program, Santa Clara University; and
- Patty McCarthy Metcalf, Executive Director, Faces and Voices of Recovery.

On May 17, 2018, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 5795, as amended, favorably reported to the House by a record vote of 35 yeas and 17 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

COMMITTEE ON ENERGY AND COMMERCE -- 115TH CONGRESS
ROLL CALL VOTE # 73

BILL: H.R. 5795, Overdose Prevention and Patient Safety Act

AMENDMENT: An amendment offered by Mr. Pallone, No. 2, to direct the Secretary of the Department of Health and Human Services to identify and disseminate model programs and materials for training health care providers concerning the permitted uses and disclosures for the confidentiality of patient records, and model programs and materials for training patients and their families regarding their rights to protect and obtain information; to direct the Secretary to support a study, and report to Congress, that examines information sharing behaviors of individuals who obtain substance use disorder treatment through a Part 2 program; and to direct the Secretary to enter into an agreement with the National Academies of Science, Engineering, and Medicine to review the role of privacy in substances use disorder treatment.

DISPOSITION: NOT AGREED TO, by a roll call vote of 23 yeas and 29 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Walden		X		Mr. Pallone	X		
Mr. Barton	X			Mr. Rush	X		
Mr. Upton		X		Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Engel	X		
Mr. Burgess		X		Mr. Green	X		
Mrs. Blackburn				Ms. DeGette			
Mr. Scalise				Mr. Doyle		X	
Mr. Latta		X		Ms. Schakowsky	X		
Mrs. McMorris Rodgers		X		Mr. Butterfield	X		
Mr. Harper		X		Ms. Matsui	X		
Mr. Lance		X		Ms. Castor	X		
Mr. Guthrie		X		Mr. Sarbanes	X		
Mr. Olson		X		Mr. McNerney	X		
Mr. McKinley		X		Mr. Welch	X		
Mr. Kinzinger		X		Mr. Lujan	X		
Mr. Griffith		X		Mr. Tonko	X		
Mr. Bilirakis		X		Ms. Clarke	X		
Mr. Johnson		X		Mr. Loebsack	X		
Mr. Long		X		Mr. Schrader	X		
Mr. Bucshon		X		Mr. Kennedy	X		
Mr. Flores		X		Mr. Cardenas	X		
Mrs. Brooks		X		Mr. Ruiz	X		
Mr. Mullin		X		Mr. Peters	X		
Mr. Hudson		X		Ms. Dingell	X		
Mr. Collins		X					
Mr. Cramer		X					
Mr. Walberg		X					
Mrs. Walters		X					
Mr. Costello		X					
Mr. Carter		X					
Mr. Duncan		X					

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COMMITTEE ON ENERGY AND COMMERCE -- 115TH CONGRESS
ROLL CALL VOTE # 74

BILL: H.R. 5795, Overdose Prevention and Patient Safety Act

AMENDMENT: A motion by Mr. Walden to order H.R. 5795 favorably reported to the House, as amended. (Final Passage)

DISPOSITION: AGREED TO, by a roll call vote of 35 yeas and 17 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Walden	X			Mr. Pallone		X	
Mr. Barton		X		Mr. Rush		X	
Mr. Upton	X			Ms. Eshoo	X		
Mr. Shimkus	X			Mr. Engel		X	
Mr. Burgess	X			Mr. Green	X		
Mrs. Blackburn				Ms. DeGette			
Mr. Scalise				Mr. Doyle	X		
Mr. Latta	X			Ms. Schakowsky		X	
Mrs. McMorris Rodgers	X			Mr. Butterfield		X	
Mr. Harper	X			Ms. Matsui		X	
Mr. Lance	X			Ms. Castor		X	
Mr. Guthrie	X			Mr. Sarbanes		X	
Mr. Olson	X			Mr. McNerney		X	
Mr. McKinley	X			Mr. Welch	X		
Mr. Kinzinger	X			Mr. Lujan		X	
Mr. Griffith	X			Mr. Tonko		X	
Mr. Bilirakis	X			Ms. Clarke		X	
Mr. Johnson	X			Mr. Loebsack		X	
Mr. Long	X			Mr. Schrader	X		
Mr. Bucshon	X			Mr. Kennedy		X	
Mr. Flores	X			Mr. Cardenas		X	
Mrs. Brooks	X			Mr. Ruiz	X		
Mr. Mullin	X			Mr. Peters	X		
Mr. Hudson	X			Ms. Dingell		X	
Mr. Collins	X						
Mr. Cramer	X						
Mr. Walberg	X						
Mrs. Walters	X						
Mr. Costello	X						
Mr. Carter	X						
Mr. Duncan	X						

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OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held hearings and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 5795 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2018.

Hon. GREG WALDEN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed document with cost estimates for the opioid-related legislation ordered to be reported on May 9 and May 17, 2018.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Tom Bradley and Chad Chirico.

Sincerely,

MARK P. HADLEY
(For Keith Hall, Director).

Enclosure.

Opioid Legislation

Summary: On May 9 and May 17, 2018, the House Committee on Energy and Commerce ordered 59 bills to be reported related to the nation's response to the opioid epidemic. Generally, the bills would:

- Provide grants to facilities and providers that treat people with substance use disorders,
- Direct various agencies within the Department of Health and Human Services (HHS) to explore nonopioid approaches to treating pain and to educate providers about those alternatives,
- Modify requirements under Medicaid and Medicare for prescribing controlled substances,
- Expand Medicaid coverage for substance abuse treatment, and
- Direct the Food and Drug Administration (FDA) to modify its oversight of opioid drugs and other medications that are used to manage pain.

Because of the large number of related bills ordered reported by the Committee, CBO is publishing a single comprehensive document that includes estimates for each piece of legislation.

CBO estimates that enacting 20 of the bills would affect direct spending, and 2 of the bills would affect revenues; therefore, pay-as-you-go procedures apply for those bills.

CBO estimates that enacting H.R. 4998, the Health Insurance for Former Foster Youth Act, would increase net direct spending by more than $2.5 billion and on-budget deficits by more than $5 billion in at least one of the four consecutive 10-year periods beginning in 2029. None of the remaining 58 bills included in this estimate would increase net direct spending by more than $2.5 billion or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2029.

One of the bills reviewed for this document, H.R. 5795, would impose both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the costs of those mandates on public and private entities would fall below the thresholds in UMRA ($80 million and $160 million, respectively, in 2018, adjusted annually for inflation). Five bills, H.R. 5228, H.R. 5333, H.R. 5554, H.R. 5687, and H.R. 5811, would impose private-sector mandates as defined in UMRA. CBO estimates that the costs of the mandates in three of the bills (H.R. 5333, H.R. 5554, and H.R. 5811) would not exceed the UMRA threshold for private entities. Because CBO is uncertain how federal agencies would implement new authority granted in the other two bills, H.R. 5228 and H.R. 5687, CBO cannot determine whether the costs of those mandates would exceed the UMRA threshold.

Estimated cost to the Federal Government: The estimates in this document do not include the effects of interactions among the bills. If all 59 bills were combined and enacted as one piece of legislation, the budgetary effects would be different from the sum of the estimates in this document, although CBO expects that any such differences would be small. The costs of this legislation fall within budget functions 550 (health), 570 (Medicare), 750 (administration of justice), and 800 (general government).

Basis of estimate: For this estimate, CBO assumes that all of the legislation will be enacted late in 2018 and that authorized and estimated amounts will be appropriated each year. Outlays for discretionary programs are estimated based on historical spending patterns for similar programs.

Uncertainty

CBO aims to produce estimates that generally reflect the middle of a range of the most likely budgetary outcomes that would result if the legislation was enacted. Because data on the utilization of mental health and substance abuse treatment under Medicaid and Medicare is scarce, CBO cannot precisely predict how patients or providers would respond to some policy changes or what budgetary effects would result. In addition, several of the bills would give the Department of Health and Human Services (HHS) considerable latitude in designing and implementing policies. Budgetary effects could differ from those provided in CBO's analyses depending on those decisions.

Direct spending and revenues

Table 1 lists the 22 bills of the 59 ordered to be reported that would affect direct spending or revenues.

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING AND REVENUES

	By fiscal year, in millions of dollars—												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019–2023	2019–2028
INCREASES OR DECREASES (−) IN DIRECT SPENDING													
Legislation Primarily Affecting Medicaid:													
H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017	0	*	5	5	5	10	10	10	10	10	10	25	75
H.R. 4998, Health Insurance for Former Foster Youth Act	0	0	0	0	0	*	10	21	33	46	61	*	171
H.R. 5477, Rural Development of Opioid Capacity Services Act	0	13	35	58	68	83	27	9	3	3	3	256	301
H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5797, IMD CARE Act	0	38	158	251	265	279	0	0	0	0	0	991	991
H.R. 5799, Medicaid DRUG Improvement Act [a]	0	*	*	1	1	1	1	1	1	1	1	2	5
H.R. 5801 Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act [a]	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 [a]	0	*	−1	−1	−1	−1	−2	−2	−2	−2	−2	−4	−13
H.R. 5810, Medicaid Health HOME Act	0	94	58	62	56	52	48	43	38	32	25	323	509
Legislation Primarily Affecting Medicare:													
H.R. 3528, Every Prescription Conveyed Securely Act	0	0	0	−24	−35	−33	−30	−33	−32	−31	−32	−92	−250
H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018	0	0	0	*	*	*	*	*	*	*	*	*	*
H.R. 5603, Access to Telehealth Services for Opioid Use Disorders Act	0	2	*	*	*	1	1	1	2	2	2	3	11
H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act	0	0	0	15	26	24	23	23	10	1	*	65	122
H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries	0	0	0	−6	−7	−7	−7	−8	−9	−9	−11	−20	−64
H.R. 5684, Protecting Seniors From Opioid Abuse Act	0	0	0	*	*	*	*	*	*	*	*	*	*
H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018	0	10	25	50	10	5	0	0	0	0	0	100	100
H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act	0	0	*	1	1	1	1	1	1	1	1	2	5
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act [a]	0	0	25	30	25	20	10	5	0	0	0	100	115
H.R. 5809, Postoperative Opioid Prevention Act of 2018	0	0	0	0	10	15	20	25	30	35	45	25	180
Legislation Primarily Affecting the Food and Drug Administration:													

H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018 [a]	0	0	*	*	*	*	*	*	*	*	*	*	*
INCREASES OR DECREASES (−) IN REVENUES [b]													
H.R. 5752, Stop Illicit Drug Importation Act of 2018	0	*	*	*	*	*	*	*	*	*	*	*	*

Annual amounts may not sum to totals because of rounding. * = between −$500,000 and $500,000. Budget authority is equivalent to outlays.

[a] This bill also would affect spending subject to appropriation.

[b] One additional bill, H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would have a negligible effect on revenues.

Legislation Primarily Affecting Medicaid. The following nine bills would affect direct spending for the Medicaid program.

H.R. 1925, the At-Risk Youth Medicaid Protection Act of 2017, would require states to suspend, rather than terminate, Medicaid eligibility for juvenile enrollees (generally under 21 years of age) who become inmates of public correctional institutions. States also would have to redetermine those enrollees' Medicaid eligibility before their release and restore their coverage upon release if they qualify for the program. States would be required to process Medicaid applications submitted by or on behalf of juveniles in public correctional institutions who were not enrolled in Medicaid before becoming inmates and ensure that Medicaid coverage is provided when they are released if they are found to be eligible. On the basis of an analysis of juvenile incarceration trends and of the per enrollee spending for Medicaid foster care children, who have a similar health profile to incarcerated juveniles, CBO estimates that implementing the bill would cost $75 million over the 2019–2028 period.

H.R. 4998, the Health Insurance for Former Foster Youth Act, would require states to provide Medicaid coverage to adults up to age 25 who had aged out of foster care in any state. Under current law, such coverage is mandatory only if the former foster care youth has aged out in the state in which the individual applies for coverage. The policy also would apply to former foster children who had been in foster care upon turning 14 years of age but subsequently left foster care to enter into a legal guardianship with a kinship caregiver. The provisions would take effect respect for foster youth who turn 18 on or after January 1, 2023. On the basis of spending for Medicaid foster care children and data from the Census Bureau regarding annual migration rates between states, CBO estimates that implementing the bill would cost $171 million over the 2019–2028 period.

H.R. 5477, the Rural Development of Opioid Capacity Services Act, would direct the Secretary of HHS to conduct a five-year demonstration to increase the number and ability of providers participating in Medicaid to provide treatment for substance use disorders. On the basis of an analysis of federal and state spending for treatment of substance use disorders and the prevalence of such disorders, CBO estimates that enacting the bill would increase direct spending by $301 million over the 2019–2028 period.

H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes, would require states to include behavioral health indicators in their annual reports on the quality of care under Medicaid. Although the bill would add a requirement for states, CBO estimates that its enactment would not have a significant budgetary effect because most states have systems in place for reporting such measures to the federal government.

H.R. 5797, the IMD CARE Act, would expand Medicaid coverage for people with opioid use disorder who are in institutions for mental disease (IMDs) for up to 30 days per year. Under a current-law policy known as the IMD exclusion, the federal government generally does not make matching payments to state Medicaid programs for most services provided by IMDs to adults between the ages of 21 and 64. Recent administrative changes have made fed-

eral financing for IMDs available in limited circumstances, but the statutory prohibition remains in place. CBO analyzed several data sets, primarily those collected by the Substance Abuse and Mental Health Services Administration (SAMHSA), to estimate current federal spending under Medicaid for IMD services and to estimate spending under H.R. 5797. Using that analysis, CBO estimates that enacting H.R. 5797 would increase direct spending by $991 million over the 2019–2028 period.

H.R. 5799, the Medicaid DRUG Improvement Act, would require state Medicaid programs to implement additional reviews of opioid prescriptions, monitor concurrent prescribing of opioids and certain other drugs, and monitor use of antipsychotic drugs by children. CBO estimates that the bill would increase direct spending by $5 million over 2019–2028 period to cover the administrative costs of complying with those requirements. On the basis of stakeholder feedback, CBO expects that the bill would not have a significant effect on Medicaid spending for prescription drugs because many of the bill's requirements would duplicate current efforts to curb opioid and antipsychotic drug use. (If enacted, H.R. 5799 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5801, the Medicaid Providers Are Required To Note Experiences in Record Systems to Help-In-Need Patients (PARTNERSHIP) Act, would require providers who are permitted to prescribe controlled substances and who participate in Medicaid to query prescription drug monitoring programs (PDMPs) before prescribing controlled substances to Medicaid patients. PDMPs are statewide electronic databases that collect data on controlled substances dispensed in the state. The bill also would require PDMPs to comply with certain data and system criteria, and it would provide additional federal matching funds to certain states to help cover administrative costs. On the basis of a literature review and stakeholder feedback, CBO estimates that the net budgetary effect of enacting H.R. 5801 would be insignificant. Costs for states to come into compliance with the systems and administrative requirements would be roughly offset by savings from small reductions in the number of controlled substances paid for by Medicaid under the proposal. (If enacted, H.R. 5801 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5808, the Medicaid Pharmaceutical Home Act of 2018, would require state Medicaid programs to operate pharmacy programs that would identify people at high risk of abusing controlled substances and require those patients to use a limited number of providers and pharmacies. Although nearly all state Medicaid programs currently meet such a requirement, a small number of high-risk Medicaid beneficiaries are not now monitored. Based on an analysis of information about similar state and federal programs, CBO estimates that net Medicaid spending under the bill would decrease by $13 million over the 2019–2028 period. That amount represents a small increase in administrative costs and a small reduction in the number of controlled substances paid for by Medicaid under the proposal. (If enacted, H.R. 5808 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5810, the Medicaid Health HOME Act, would allow states to receive six months of enhanced federal Medicaid funding for programs that coordinate care for people with substance use disorders. Based on enrollment and spending data from states that currently participate in Medicaid's Health Homes program, CBO estimates that the expansion would cost approximately $469 million over the 2019–2028 period. The bill also would require states to cover all FDA-approved drugs used in medication-assisted treatment for five years, although states could seek a waiver from that requirement. (Medication-assisted treatment combines behavioral therapy and pharmaceutical treatment for substance use disorders.) Under current law, states already cover most FDA-approved drugs used in such programs in some capacity, although a few exclude methadone dispensed by opioid treatment programs. CBO estimates that a small share of those states would begin to cover methadone if this bill was enacted at a federal cost of about $39 million over the 2019–2028 period. In sum, CBO estimates that the enacting H.R. 5810 would increase direct spending by $509 million over the 2019–2028 period.

Legislation Primarily Affecting Medicare. The following ten bills would affect direct spending for the Medicare program.

H.R. 3528, the Every Prescription Conveyed Securely Act, would require prescriptions for controlled substances covered under Medicare Part D to be transmitted electronically, starting on January 1, 2021. Based on CBO's analysis of prescription drug spending, spending for controlled substances is a small share of total drug spending. CBO also assumes a small share of those prescriptions would not be filled because they are not converted to an electronic format. Therefore, CBO expects that enacting H.R. 3528 would reduce the number of prescriptions filled and estimates that Medicare spending be reduced by $250 million over the 2019–2028 period.

H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018, would require health care professionals to submit prior authorization requests electronically, starting on January 1, 2021, for drugs covered under Medicare Part D. Taking into account that many prescribers already use electronic methods to submit such requests, CBO estimates that enacting H.R. 4841 would not significantly affect direct spending for Part D.

H.R. 5603, the Access to Telehealth Services for Opioid Use Disorders Act, would permit the Secretary of HHS to lift current geographic and other restrictions on coverage of telehealth services under Medicare for treatment of substance use disorders or co-occurring mental health disorders. Under the bill, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration. Based on current use of Medicare telehealth services for treatment of substance use disorders, CBO estimates that expanding that coverage would increase direct spending by $11 million over the 2019–2028 period.

H.R. 5605, the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act, would establish a five-year demonstra-

tion program to increase access to treatment for opioid use disorder. The demonstration would provide incentive payments and funding for care management services based on criteria such as patient engagement, use of evidence-based treatments, and treatment length and intensity. Under the bill, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration. Based on historical utilization of opioid use disorder treatments and projected spending on incentive payments and care management fees, CBO estimates that increased use of treatment services and the demonstration's incentive payments would increase direct spending by $122 million over the 2019–2028 period.

H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries, would require Part D prescription drug plans to provide drug management programs for Medicare beneficiaries who are at risk for prescription drug abuse. (Under current law, Part D plans are permitted but not required to establish such programs as of 2019.) Based on an analysis of the number of plans currently providing those programs, CBO estimates that enacting H.R. 5675 would lower federal spending by $64 million over the 2019–2028 period by reducing the number of prescriptions filled and Medicare's payments for controlled substances.

H.R. 5684, the Protecting Seniors From Opiod Abuse Act, would expand medication therapy management programs under Medicare Part D to include beneficiaries who are at risk for prescription drug abuse. Because relatively few beneficiaries would be affected by this bill, CBO estimates that its enactment would not significantly affect direct spending for Part D.

H.R. 5796, the Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018, would allow the Secretary of HHS to award grants to certain organizations that provide technical assistance and education to high-volume prescribers of opioids. The bill would appropriate $100 million for fiscal year 2019. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5796 would cost $100 million over the 2019–2028 period.

H.R. 5798, the Opioid Screening and Chronic Pain Management Alternatives for Seniors Act, would add an assessment of current opioid prescriptions and screening for opioid use disorder to the Welcome to Medicare Initial Preventive Physical Examination. Based on historical use of the examinations and pain management alternatives, CBO expects that enacting the bill would increase use of pain management services and estimates that direct spending would increase by $5 million over the 2019–2028 period.

H.R. 5804, the Post-Surgical Injections as an Opioid Alternative Act, would freeze the Medicare payment rate for certain analgesic injections provided in ambulatory surgical centers (ASCs). (For injections identified by specific billing codes, Medicare would pay the 2016 rate, which is higher than the current rate, during the 2020–2024 period.) Based on current utilization in the ASC setting, CBO

estimates that enacting the legislation would increase direct spending by about $115 million over the 2019–2028 period. (If enacted, H.R. 5804 also would affect spending subject to appropriation; see Table 3.)

H.R. 5809, the Postoperative Opioid Prevention Act of 2018, would create an additional payment under Medicare for nonopioid analgesics. Under current law, certain new drugs and devices may receive an additional payment—separate from the bundled payment for a surgical procedure—in outpatient hospital departments and ambulatory surgical centers. The bill would allow nonopioid analgesics to qualify for a five-year period of additional payments. Based on its assessment of current spending for analgesics and on the probability of new nonopioid analgesics coming to market, CBO estimates that H.R. 5809 would increase direct spending by about $180 million over the 2019–2028 period.

Legislation Primarily Affecting the Food and Drug Administration. One bill related to the FDA would affect direct spending.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would change the way that the FDA regulates the marketing of over-the-counter (OTC) medicines, and it would authorize that agency to grant 18 months of exclusive market protection for certain qualifying OTC drugs, thus delaying the entry of other versions of the same qualifying OTC product. Medicaid currently provides some coverage for OTC medicines, but only if a medicine is the least costly alternative in its drug class. On the basis of stakeholder feedback, CBO expects that delaying the availability of additional OTC versions of a drug would not significantly affect the average net price paid by Medicaid. As a result, CBO estimates that enacting H.R. 5333 would have a negligible effect on the federal budget. (If enacted, H.R. 5333 also would affect spending subject to appropriation; see Table 3.)

Legislation with Revenue Effects. Two bills would affect revenues. However, CBO estimates that one bill, H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would have only a negligible effect.

H.R. 5752, the Stop Illicit Drug Importation Act of 2018, would amend the Federal, Food, Drug, and Cosmetic Act (FDCA) to strengthen the FDA's seizure powers and enhance its authority to detain, refuse, seize, or destroy illegal products offered for import. The legislation would subject more people to debarment under the FDCA and thus increase the potential for violations, and subsequently, the assessment of civil penalties, which are recorded in the budget as revenues. CBO estimates that those collections would result in an insignificant increase in revenues. Because H.R. 5752 would prohibit the importation of drugs that are in the process of being scheduled, it also could reduce amounts collected in customs duties. CBO anticipates that the result would be a negligible decrease in revenues. With those results taken together, CBO estimates, enacting H.R. 5752 would generate an insignificant net increase in revenues over the 2019–2028 period.

Spending subject to appropriation

For this document, CBO has grouped bills with spending that would be subject to appropriation into four general categories:

- Bills that would have no budgetary effect,

- Bills with provisions that would authorize specified amounts to be appropriated (see Table 2),
- Bills with provisions for which CBO has estimated an authorization of appropriations (see Table 3), and
- Bills with provisions that would affect spending subject to appropriation for which CBO has not yet completed an estimate.

No Budgetary Effect. CBO estimates that 6 of the 59 bills would have no effect on direct spending, revenues, or spending subject to appropriation.

H.R. 3192, the CHIP Mental Health Parity Act, would require all Children's Health Insurance Program (CHIP) plans to cover mental health and substance abuse treatment. In addition, states would not be allowed to impose financial or utilization limits on mental health treatment that are lower than limits placed on physical health treatment. Based on information from the Centers for Medicare and Medicaid Services, CBO estimates that enacting the bill would have no budgetary effect because all CHIP enrollees are already in plans that meet those requirements.

H.R. 3331, a bill to amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology, would give the Center for Medicare and Medicaid Innovation (CMMI) explicit authorization to test a program offering incentive payments to behavioral health providers that adopt and use certified electronic health record technology. Because it is already clear to CMMI that it has that authority, CBO estimates that enacting the legislation would not affect federal spending.

H.R. 5202, the Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018, would clarify permission for pharmacists to deliver controlled substances to providers under certain circumstances. Because this provision would codify current practice, CBO estimates that H.R. 5202 would not affect direct spending or revenues during the 2019–2028 period.

H.R. 5685, the Medicare Opioid Safety Education Act of 2018, would require the Secretary of HHS to include information on opioid use, pain management, and nonopioid pain management treatments in future editions of *Medicare & You*, the program's handbook for beneficiaries, starting on January 1, 2019. Because H.R. 5685 would add information to an existing administrative document, CBO estimates that enacting the bill would have no budgetary effect.

H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018, would require prescription drug plans that provide coverage under Medicare Part D to furnish information to beneficiaries about the risks of opioid use and the availability of alternative treatments for pain. CBO estimates that enacting the bill would not affect direct spending because the required activities would not impose significant administrative costs.

H.R. 5716, the Commit to Opioid Medical Prescriber Accountability and Safety for Seniors Act, would require the Secretary of HHS on an annual basis to identify high prescribers of opioids and furnish them with information about proper prescribing methods. Because HHS already has the capacity to meet those requirements,

CBO estimates that enacting that provision would not impose additional administrative costs on the agency.

Specified Authorizations. Table 2 lists the ten bills that would authorize specified amounts to be appropriated over the 2019–2023 period. Spending from those authorized amounts would be subject to appropriation.

TABLE 2.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH SPECIFIED AUTHORIZATIONS

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 4684, Ensuring Access to Quality Sober Living Act:							
Authorization Level	0	3	0	0	0	0	3
Estimated Outlays	0	1	2	*	*	*	3
H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018:							
Authorization Level	0	25	25	25	25	25	125
Estimated Outlays	0	9	19	23	25	25	100
H.R. 5176, Preventing Overdoses While in Emergency Rooms Act of 2018:							
Authorization Level	0	50	0	0	0	0	50
Estimated Outlays	0	16	26	6	2	1	50
H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act:							
Authorization Level	0	10	10	10	0	0	30
Estimated Outlays	0	3	8	10	7	2	30
H.R. 5261, Treatment, Education, and Community Help to Combat Addiction Act of 2018:							
Authorization Level	0	4	4	4	4	4	20
Estimated Outlays	0	1	3	4	4	4	16
H.R. 5327, Comprehensive Opioid Recovery Centers Act of 2018:							
Authorization Level	0	10	10	10	10	10	50
Estimated Outlays	0	3	8	10	10	10	41
H.R. 5329, Poison Center Network Enhancement Act of 2018:							
Authorization Level	0	30	30	30	30	30	151
Estimated Outlays	0	12	25	29	29	29	125
H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act of 2018:							
Authorization Level	0	40	40	40	40	40	200
Estimated Outlays	0	15	34	38	39	40	166
H.R. 5580, Surveillance and Testing of Opioids to Prevent Fentanyl Deaths Act of 2018:							
Authorization Level	30	30	30	30	30	0	120
Estimated Outlays	0	11	25	29	29	19	113
H.R. 5587, Peer Support Communities of Recovery Act:							
Authorization Level	0	15	15	15	15	15	75
Estimated Outlays	0	5	13	14	15	15	62

Annual amounts may not sum to totals because of rounding. * = between zero and $500,000.

H.R. 4684, the Ensuring Access to Quality Sober Living Act, would direct the Secretary of HHS to develop and disseminate best practices for organizations that operate housing designed for people recovering from substance use disorders. The bill would authorize a total of $3 million over the 2019–2021 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 4684 would cost $3 million over the 2019–2023 period.

H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act of 2018, would establish a loan repayment program for mental health professionals who practice in areas with few mental health providers or with high rates of death from overdose and would authorize $25 million per year over the 2019–2028 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5102 would cost $100 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act of 2018, would require the Secretary of HHS to develop protocols and a grant program for health care providers to address the needs of people who survive a drug overdose, and it would authorize $50 million in 2019 for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5176 would cost $50 million over the 2019–2023 period.

H.R. 5197, the Alternatives to Opioids (ALTO) in the Emergency Department Act, would direct the Secretary of HHS to carry out a demonstration program for hospitals and emergency departments to develop alternative protocols for pain management that limit the use of opioids and would authorize $10 million annually in grants for fiscal years 2019 through 2021. Based on historical spending patterns for similar programs, CBO estimates that implementing H.R. 5197 would cost $30 million over the 2019–2023 period.

H.R. 5261, the Treatment, Education, and Community Help to Combat Addiction Act of 2018, would direct the Secretary of HHS to designate regional centers of excellence to improve the training of health professionals who treat substance use disorders. The bill would authorize $4 million annually for grants to those programs over the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5261 would cost $16 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5327, the Comprehensive Opioid Recovery Centers Act of 2018, would direct the Secretary of HHS to award grants to at least 10 providers that offer treatment services for people with opioid use disorder, and it would authorize $10 million per year over the 2019–2023 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5327 would cost $41 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5329, the Poison Center Network Enhancement Act of 2018, would reauthorize the poison control center toll-free number, national media campaign, and grant program under the Public Health Service Act. Among other actions, H.R. 5329 would increase the share of poison control center funding that could be provided by federal grants. The bill would authorize a total of about $30 million per year over the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5329 would cost $125 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R 5353, the Eliminating Opioid Related Infectious Diseases Act of 2018, would amend Public Health Service Act by broadening the focus of surveillance and education programs from preventing and

treating hepatitis C virus to preventing and treating infections associated with injection drug use. It would authorize $40 million per year over 2019–2023 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5353 would cost $166 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5580, the Surveillance and Testing of Opioids to Prevent Fentanyl Deaths Act of 2018, would establish a grant program for public health laboratories that conduct testing for fentanyl and other synthetic opioids. It also would direct the Centers for Disease Control and Prevention to expand its drug surveillance program, with a particular focus on collecting data on fentanyl. The bill would authorize a total of $30 million per year over the 2018–2022 period for those activities. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5580 would cost $113 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5587, Peer Support Communities of Recovery Act, would direct the Secretary of HHS to award grants to nonprofit organizations that support community-based, peer-delivered support, including technical support for the establishment of recovery community organizations, independent, nonprofit groups led by people in recovery and their families. The bill would authorize $15 million per year for the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5587 would cost $62 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

Estimated Authorizations. Table 3 shows CBO's estimates of the appropriations that would be necessary to implement 19 of the bills. Spending would be subject to appropriation of those amounts.

H.R. 449, the Synthetic Drug Awareness Act of 2018, would require the Surgeon General to report to the Congress on the health effects of synthetic psychoactive drugs on children between the ages of 12 and 18. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 449 would cost approximately $1 million over the 2019–2023 period.

H.R. 4005, the Medicaid Reentry Act, would direct the Secretary of HHS to convene a group of stakeholders to develop and report to the Congress on best practices for addressing issues related to health care faced by those returning from incarceration to their communities. The bill also would require the Secretary to issue a letter to state Medicaid directors about relevant demonstration projects. Based on an analysis of anticipated workload, CBO estimates that implementing H.R. 4005 would cost less than $500,000 over the 2018–2023 period.

H.R. 4275, the Empowering Pharmacists in the Fight Against Opioid Abuse Act, would require the Secretary of HHS to develop and disseminate materials for training pharmacists, health care practitioners, and the public about the circumstances under which a pharmacist may decline to fill a prescription. Based on historical spending patterns for similar activities, CBO estimates that costs to the federal government for the development and distribution of those materials would not be significant.

TABLE 3.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 449, Synthetic Drug Awareness Act of 2018:							
Estimated Authorization Level	0	*	*	*	0	0	1
Estimated Outlays	0	*	*	*	0	0	1
H.R. 4005, Medicaid Reentry Act:							
Estimated Authorization Level	*	*	0	0	0	0	*
Estimated Outlays	*	*	0	0	0	0	*
H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5009, Jessie's Law:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5041, Safe Disposal of Unused Medication Act:	0	*	*	*	*	*	*
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018:							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018: [a]							
Food and Drug Administration:							
Collections from fees:							
Estimated Authorization Level	0	−22	−22	−26	−35	−42	−147
Estimated Outlays	0	−22	−22	−26	−35	−42	−147
Spending of fees:							
Estimated Authorization Level	0	22	22	26	35	42	147
Estimated Outlays	0	6	17	30	44	41	137
Net effect on FDA:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	−17	−6	4	9	*	−10
Government Accountability Office:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	0	0	0	0	*	*
Total, H.R. 5333:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	−17	−6	4	9	*	−10
H.R. 5473, Better Pain Management Through Better Data Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	0	1
Estimated Outlays	0	*	*	*	*	*	1
H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5554, Animal Drug and Animal Generic Drug User Fee Amendments of 2018:							
Collections from fees:							
Animal drug fees	0	−30	−31	−32	−33	−34	−159
Generic animal drug fees	0	−18	−19	−19	−20	−21	−97
Total, Estimated Authorization Level	0	−49	−50	−51	−53	−55	−257
Total, Estimated Outlays	0	−40	−50	−51	−53	−55	−257
Spending of fees:							
Animal drug fees	0	30	31	32	33	34	159
Generic animal drug fees	0	18	19	19	20	21	97
Total, Estimated Authorization Level	0	49	50	51	53	55	257
Total, Estimated Outlays	0	39	47	51	52	54	243

TABLE 3.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS—Continued

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
Net changes in fees:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	−10	−3	*	*	*	−14
Other effects:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	2	1	1	1	1	6
Total, H.R. 5554:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	−8	−2	1	*	*	−8
H.R. 5582, Abuse Deterrent Access Act of 2018:							
Estimated Authorization Level	0	0	*	0	0	0	*
Estimated Outlays	0	0	*	0	0	0	*
H.R. 5590, Opioid Addiction Action Plan Act:							
Estimated Authorization Level	*	*	*	*	*	*	2
Estimated Outlays	*	*	*	*	*	*	2
H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act:							
Estimated Authorization Level	0	2	2	2	2	2	9
Estimated Outlays	0	2	2	2	2	2	9
H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder:							
Estimated Authorization Level	0	2	0	0	0	0	2
Estimated Outlays	0	2	0	0	0	0	2
H.R. 5795, Overdose Prevention and Patient Safety Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	1	0	0	0	0	1
H.R. 5800, Medicaid IMD ADDITIONAL INFO Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	*	*	0	0	0	1
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act: [a]							
Estimated Authorization Level	0	0	0	0	1	1	1
Estimated Outlays	0	0	0	0	1	1	1
H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*

Annual amounts may not sum to totals because of rounding. * = between −$500,000 and $500,000.
[a] This bill also would affect mandatory spending (see Table 1).

H.R. 5009, Jessie's Law, would require HHS, in collaboration with outside experts, to develop best practices for displaying information about opioid use disorder in a patient's medical record. HHS also would be required to develop and disseminate written materials annually to health care providers about what disclosures could be made while still complying with federal laws that govern health care privacy. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 5009 would have an insignificant effect on spending over the 2019–2023 period.

H.R. 5041, the Safe Disposal of Unused Medication Act, would require hospice programs to have written policies and procedures for the disposal of controlled substances after a patient's death. Certain licensed employees of hospice programs would be permitted to assist in the disposal of controlled substances that were lawfully dispensed. Using information from the Department of Justice (DOJ), CBO estimates that implementing the bill would cost less than $500,000 over the 2019–2023 period.

H.R. 5272, the Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018, would require the newly established National Mental Health and Substance Use Policy Laboratory to issue guidance to applicants for SAMHSA grants that support evidence-based practices. Using information from HHS about the historical cost of similar activities, CBO estimates that enacting this bill would cost approximately $4 million over the 2019–2023 period.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would change the FDA's oversight of the commercial marketing of OTC medicines and authorize the collection and spending of fees through 2023 to cover the costs of expediting the FDA's administrative procedures for certain regulatory activities relating to OTC products. Under H.R. 5333, CBO estimates, the FDA would assess about $147 million in fees over the 2019–2023 period that could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. Because the FDA could spend those fees, CBO estimates that the estimated budget authority for collections and spending would offset each other exactly in each year, although CBO expects that spending initially would lag behind collections. Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 5333 would reduce net discretionary outlays by $10 million over the 2019–2023 period, primarily because of that lag. The bill also would require the Government Accountability Office to study exclusive market protections for certain qualifying OTC drugs authorized by the bill—a provision that CBO estimates would cost less than $500,000. (If enacted, H.R. 5333 also would affect mandatory spending; see Table 1.)

H.R. 5473, the Better Pain Management Through Better Data Act of 2018, would require that the FDA conduct a public meeting and issue guidance to industry addressing data collection and labeling for medical products that reduce pain while enabling the reduction, replacement, or avoidance of oral opioids. Using information from the agency, CBO estimates that implementing H.R. 5473 would cost about $1 million over the 2019–2023 period.

H.R. 5483, the Special Registration for Telemedicine Clarification Act of 2018, would direct DOJ, within one year of the bill's enactment, to issue regulations concerning the practice of telemedicine (for remote diagnosis and treatment of patients). Using information from DOJ, CBO estimates that implementing the bill would cost less than $500,000 over the 2019–2023 period.

H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, would authorize the FDA to collect and spend fees to cover the cost of expedited approval for the development and marketing of certain drugs for use in animals. The legislation would extend through fiscal year 2023, and make several changes

to, the FDA's existing approval processes and fee programs for brand-name and generic veterinary drugs, which expire at the end of fiscal year 2018. CBO estimates that implementing H.R. 5554 would reduce net discretionary outlays by $8 million over the 2019–2023 period, primarily because the spending of fees lags somewhat behind their collection.

Fees authorized under the bill would supplement funds appropriated to cover the FDA's cost of reviewing certain applications and investigational submissions for brand-name and generic drugs for use in animals. Those fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. Under H.R. 5554, CBO estimates, the FDA would assess about $257 million in fees over the 2019–2023 period. Because the FDA could spend those funds, CBO estimates that budget authority for collections and spending would offset each other exactly in each year. CBO estimates that the delay between collecting and spending fees under the reauthorized programs would reduce net discretionary outlays by $14 million over the 2019–2023 period, assuming appropriation actions consistent with the bill.

Enacting H.R. 5554 would increase the FDA's workload because the legislation would expand eligibility for conditional approval for certain drugs. The agency's administrative costs also would increase because of regulatory activities required by a provision concerning petitions for additives intended for use in animal food. H.R. 5554 also would require the FDA to publish guidance or produce regulations on a range of topics, transmit a report to the Congress, and hold public meetings. CBO expects that the costs associated with those activities would not be covered by fees, and it estimates that implementing such provisions would cost $6 million over the 2019–2023 period.

H.R. 5582, the Abuse Deterrent Access Act of 2018, would require the Secretary of HHS to report to the Congress on existing barriers to access to "abuse-deterrent opioid formulations" by Medicare Part C and D beneficiaries. Such formulations make the drugs more difficult to dissolve for injection, for example, and thus can impede their abuse. Assuming the availability of appropriated funds and based on historical spending patterns for similar activities, CBO estimates that implementing the legislation would cost less than $500,000 over the 2019–2023 period.

H.R. 5590, the Opioid Addiction Action Plan Act, would require the Secretary of HHS to develop an action plan by January 1, 2019, for increasing access to medication-assisted treatment among Medicare and Medicaid enrollees. The bill also would require HHS to convene a stakeholder meeting and issue a request for information within three months of enactment, and to submit a report to the Congress by June 1, 2019. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5590 would cost approximately $2 million over the 2019–2023 period.

H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018, would permit the FDA to require certain packaging and disposal technologies, controls, or measures to mitigate the risk of abuse and misuse of drugs. Based on information from the FDA, CBO estimates that implementing H.R. 5687 would not significantly affect spending over the 2019–

2023 period. This bill would also require that the GAO study the effectiveness and use of packaging technologies for controlled substances—a provision that CBO estimates would cost less than $500,000.

H.R. 5715, the Strengthening Partnerships to Prevent Opioid Abuse Act, would require the Secretary of HHS to establish a secure Internet portal to allow HHS, Medicare Advantage plans, and Medicare Part D plans to exchange information about fraud, waste, and abuse among providers and suppliers no later than two years after enactment. H.R. 5715 also would require organizations with Medicare Advantage contracts to submit information on investigations related to providers suspected of prescribing large volumes of opioids through a process established by the Secretary no later than January 2021. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5715 would cost approximately $9 million over the 2019–2023 period.

H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder, would direct the Secretary of HHS to issue guidance to states on best practices under Medicaid and CHIP for treating infants with neonatal abstinence syndrome. H.R. 5789 also would direct the Government Accountability Office to study Medicaid coverage for pregnant and postpartum women with substance use disorders. Based on inforation from HHS and historical spending patterns for similar activities, CBO estimates that enacting H.R. 5789 would cost approximately $2 million over the 2019–2023 period.

H.R. 5795, the Overdose Prevention and Patient Safety Act, would amend the Public Health Service Act so that requirements pertaining to the confidentiality and disclosure of medical records relating to substance use disorders align with the provisions of the Health Insurance Portability and Accountability Act of 1996. The bill would require the Office of the Secretary of HHS to issue regulations prohibiting discrimination based on data disclosed from such medical records, to issue regulations requiring covered entities to provide written notice of privacy practices, and to develop model training programs and materials for health care providers and patients and their families. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 5795 would cost approximately $1 million over the 2019–2023 period.

H.R. 5800, Medicaid IMD ADDITIONAL INFO Act, would direct the Medicaid and CHIP Payment and Access Commission to study institutions for mental diseases in a representative sample of states. Based on information from the commission about the cost of similar work, CBO estimates that implementing H.R. 5800 would cost about $1 million over the 2019–2023 period.

H.R. 5804, the Post-Surgical Injections as an Opioid Alternative Act, would freeze the Medicare payment rate for certain analgesic injections provided in ambulatory surgical centers. The bill also would mandate two studies of Medicare coding and payments arising from enactment of this legislation. Based on the cost of similar activities, CBO estimates that those reports would cost $1 million

over the 2019–2023 period. (If enacted, H.R. 5804 also would affect mandatory spending; see Table 1.)

H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, would allow the FDA to require that pharmaceutical manufacturers study certain drugs after they are approved to assess any potential reduction in those drugs' effectiveness for the conditions of use prescribed, recommended, or suggested in labeling. CBO anticipates that implementing H.R. 5811 would not significantly affect the FDA's costs over the 2019–2023 period.

Other Authorizations. The following nine bills would increase authorization levels, but CBO has not completed estimates of amounts. All authorizations would be subject to future appropriation action.

- H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids Act of 2017
- H.R. 5002, Advancing Cutting Edge Research Act
- H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act (see Table 1 for an estimate of the revenue effects of H.R. 5228)
- H.R. 5752, Stop Illicit Drug Importation Act of 2018 (see Table 1 for an estimate of the revenue effects of H.R. 5752)
- H.R. 5799, Medicaid DRUG Improvement Act (see Table 1 for an estimate of the direct spending effects of H.R. 5799)
- H.R. 5801, Medicaid Providers and Pharmacists Are Required to Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act (see Table 1 for an estimate of the direct spending effects of H.R. 5801)
- H.R. 5806, 21st Century Tools for Pain and Addiction Treatments Act
- H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 (see Table 1 for an estimate of the direct spending effects of H.R. 5808)
- H.R. 5812, Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act (CONNECTIONS) Act

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. Twenty-two of the bills discussed in this document contain direct spending or revenues and are subject to pay-as-you-go procedures. Details about the amount of direct spending and revenues in those bills can be found in Table 1.

Increase in long-term direct spending and deficits: CBO estimates that enacting H.R. 4998, the Health Insurance for Former Foster Youth Act, would increase net direct spending by more than $2.5 billion and on-budget deficits by more than $5 billion in at least one of the four consecutive 10-year periods beginning in 2029.

CBO estimates that none of the remaining 58 bills included in this estimate would increase net direct spending by more than $2.5 billion or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2029.

Mandates: One of the 59 bills included in this document, H.R. 5795, would impose both intergovernmental and private-sector

mandates as defined in UMRA. CBO estimates that the costs of that bill's mandates on public and private entities would fall below UMRA's thresholds ($80 million and $160 million, respectively, for public- and private-sector entities in 2018, adjusted annually for inflation).

In addition, five bills would impose private-sector mandates as defined in UMRA. CBO estimates that the costs of the mandates in three of those bills (H.R. 5333, H.R. 5554, and H.R. 5811) would fall below the UMRA threshold. Because CBO does not know how federal agencies would implement new authority granted in the other two of those five bills, H.R. 5228 and 5687, CBO cannot determine whether the costs of their mandates would exceed the threshold.

For large entitlement grant programs, including Medicaid and CHIP, UMRA defines an increase in the stringency of conditions on states or localities as an intergovernmental mandate if the affected governments lack authority to offset those costs while continuing to provide required services. Because states possess significant flexibility to alter their responsibilities within Medicaid and CHIP, the requirements imposed by various bills in the markup on state administration of those programs would not constitute mandates as defined in UMRA.

Mandates Affecting Public and Private Entities

H.R. 5795, the Overdose Prevention and Patient Safety Act, would impose intergovernmental and private-sector mandates by requiring entities that provide treatment for substance use disorders to notify patients of their privacy rights and also to notify patients in the event that the confidentiality of their records is breached. In certain circumstances, H.R. 5795 also would prohibit public and private entities from denying entry to treatment on the basis of information in patient health records. Those requirements would either supplant or narrowly expand responsibilities under existing law, and compliance with them would not impose significant additional costs. CBO estimates that the costs of the mandates would fall below the annual thresholds established in UMRA.

Mandates Affecting Private Entities

Five bills included in this document would impose private-sector mandates:

H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would require drug distributors to cease distributing any drug that the Secretary of HHS determines might present an imminent or substantial hazard to public health. CBO cannot determine what drugs could be subject to such an order nor can it determine how private entities would respond. Consequently, CBO cannot determine whether the aggregate cost of the mandate would exceed the annual threshold for private-sector mandates.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would require developers and manufacturers of OTC drugs to pay certain fees to the FDA. CBO estimates that about $30 million would be collected each year, on average, for a total of $147 million over the 2019–2023 period. Those amounts

would not exceed the annual threshold for private-sector mandates in any year during that period.

H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, would require developers and manufacturers of brand-name and generic veterinary drugs to pay application, product, establishment, and sponsor fees to the FDA. CBO estimates that about $51 million would be collected annually, on average, for a total of $257 million over the 2019–2023 period. Those amounts would not exceed the annual threshold for private-sector mandates in any year during that period.

H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018, would permit the Secretary of HHS to require drug developers and manufacturers to implement new packaging and disposal technology for certain drugs. Based on information from the agency, CBO expects that the Secretary would use the new regulatory authority provided in the bill; however, it is uncertain how or when those requirements would be implemented. Consequently, CBO cannot determine whether the aggregate cost of the mandate would exceed the annual threshold for private entities.

H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, would expand an existing mandate that requires drug developers to conduct postapproval studies or clinical trials for certain drugs. Under current law, in certain instances, the FDA can require studies or clinical trials after a drug has been approved. H.R. 5811 would permit the FDA to use that authority if the reduction in a drug's effectiveness meant that its benefits no longer outweighed its costs. CBO estimates that the incremental cost of the mandate would fall below the annual threshold established in UMRA because of the small number of drugs affected and the narrow expansion of the authority that exists under current law.

None of the remaining 53 bills included in this document would impose an intergovernmental or private-sector mandate.

Previous CBO estimate: On June 6, 2018, CBO issued an estimate for seven opioid-related bills ordered reported by the House Committee on Ways and Means on May 16, 2018. Two of those bills contain provisions that are identical or similar to the legislation ordered reported by the Committee on Energy and Commerce, and for those provisions, CBO's estimates are the same.

In particular, five bills listed in this estimate contain provisions that are identical or similar to those in several sections of H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018:

- H.R. 5675, which would require prescription drug plans to implement drug management programs, is identical to section 2 of H.R. 5773.
- H.R. 4841, regarding electronic prior authorization for prescriptions under Medicare's Part D, is similar to section 3 of H.R. 5773.
- H.R. 5715, which would mandate the creation of a new Internet portal to allow various stakeholders to exchange information, is identical to section 4 of H.R. 5773.
- H.R. 5684, which would expand medication therapy management, is the same as section 5 of H.R. 5773.

• H.R. 5716, regarding prescriber notification, is identical to section 6 of H.R. 5773.

In addition, in this estimate, a provision related to Medicare beneficiary education in H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018, is the same as a provision in section 2 of H.R. 5775, the Providing Reliable Options for Patients and Educational Resources Act of 2018, in CBO's estimate for the Committee on Ways and Means.

Estimate prepared by: Federal Costs: Rebecca Yip (Centers for Disease Control and Prevention), Mark Grabowicz (Drug Enforcement Agency), Julia Christensen, Ellen Werble (Food and Drug Administration), Emily King, Andrea Noda, Lisa Ramirez-Branum, Robert Stewart (Medicaid and Children's Health Insurance Program), Philippa Haven, Lara Robillard, Colin Yee, Rebecca Yip (Medicare), Philippa Haven (National Institutes of Health), Alice Burns, Andrea Noda (Office of the Secretary of the Department of Health and Human Services), Philippa Haven, Lori Housman, Emily King (Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration); Federal Revenues: Jacob Fabian, Peter Huether, and Cecilia Pastrone; Fact Checking: Zachary Byrum and Kate Kelly; Mandates: Andrew Laughlin.

Estimate reviewed by: Tom Bradley, Chief Health Systems and Medicare Cost Estimates Unit; Chad M. Chirico, Chief Low-Income Health Programs and Prescription Drugs Cost Estimates Unit; Sarah Masi, Special Assistant for Health; Susan Willie, Chief, Mandates Unit; Leo Lex, Deputy Assistant Director for Budget Analysis; Theresa A. Gullo, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to improve the treatment SUD by permitting the use and disclosure of relevant treatment information for the purposes of treatment, payment, and health care operations between covered entities.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5795 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 5795 contains no earmarks, limited tax benefits, or limited tariff benefits.

DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the following directed rule makings are contained in H.R. 5795:

- The Secretary of Health and Human Services, in consultation with appropriate Federal agencies, shall make such revisions to regulations as may be necessary for implementing and enforcing the amendments made by the legislation with respect to uses and disclosures of information occurring on or after the date that is 12 months after the date of enactment of the legislation.
- Not later than 1 year after the date of enactment of the legislation, the Secretary of Health and Human Services, in consultation with appropriate experts, shall update section 164.520 of title 45, Code of Federal Regulations, so that covered entities provide notice, written in plain language, of privacy practices regarding patient records referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)).

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the "Overdose Prevention and Patient Safety Act."

Section 2. Confidentiality and disclosure of records relating to substance use disorder

Subsection (a) changes the term "substance abuse" to "substance use disorder."

Subsection (b) allows for the sharing of patient records referred to in section 543(a) of the Public Health Service Act, among covered entities for the purposes of treatment, payment, and health care operations.

Subsection (c) allows for the sharing of patient records referred to in section 543(a) of the Public Health Service Act, with a public health authority so long as the information is de-identified.

Subsection (d) defines covered entity, health care operations, HIPAA privacy regulation, individually identifiable health information, payment, public health authority, and treatment.

Except as otherwise authorized by patient consent or a court order, subsection (e) prohibits patient records referred to in section 543(a) of the Public Health Service Act from being entered into evidence in any criminal prosecution or civil action before a Federal or State court; to be used as part of the record for decision in any proceeding before a Federal agency; to be used by any Federal, State, or local agency for a law enforcement purpose or law enforcement investigation of a patient; or to be used in the application of a warrant.

Subsection (f) aligns the penalties under section 543 of the Public Health Service Act with the penalties under sections 1176 and 1177 of the Social Security Act.

Subsection (g) prohibits discrimination against an individual on the basis of their patient records referred to in section 543(a) of the Public Health Service Act in admission or treatment for healthcare; hiring or terms of employment; the sale or rental of housing; and access to Federal, State, or local courts. Subsection (g) also prohibits recipients of Federal funds from discriminating against an individual on the basis of their patient records referred to in section 543(a) of the Public Health Service Act.

Subsection (h) establishes breach notification requirements of section 13402 of the HITECH Act in the case of a data breach of information referred to in section 543(a) of the Public Health Service Act.

Subsection (i) states that it is the sense of Congress that any person treating a patient through a program or activity with respect to which the requirements of section 543 of the Public Health Service Act apply should access the applicable State-based prescription drug monitoring program as a precaution against substance use disorder.

Subsection (j) requires the Secretary of Health and Human Services, in consultation with appropriate Federal agencies, to make revisions to regulations as may be necessary for implementing and enforcing the amendments made by the legislation. The Secretary of Health and Human Services must update Federal regulations so that covered entities provide notice, written in plain language, of privacy practices regarding patient records referred to in section 543(a) of the Public Health Service Act.

Subsection (k) requires the Secretary of Health and Human Services to create model programs and materials to train health care providers on the permitted uses and disclosures of patient records referred to in section 543(a) of the Public Health Service Act. The Secretary must also create model programs and materials for teaching patients and their families their rights to protect and obtain information under section 543 of the Public Health Service Act.

Subsection (l) states that nothing in this legislation shall be construed to limit a patient's right to request a restriction on the use or disclosure of a record referred to in section 543(a) of the Public Health Service Act for purposes of treatment, payment, or health care operations. Subsection (l) also states that nothing in this legislation shall be construed to limit a covered entity's choice to obtain the consent of the individual to use or disclose such record to carry out treatment, payment, or health care operations.

Subsection (m) states that it is the sense of Congress that patients have the right to request a restriction on the use or disclosure of a record referred to in section 543(a) of the Public Health Service Act for treatment, payment, or health care operations, and that covered entities should make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding such use or disclosure.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE V—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

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PART D—MISCELLANEOUS PROVISIONS RELATING TO SUBSTANCE ABUSE AND MENTAL HEALTH

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SEC. 543. CONFIDENTIALITY OF RECORDS.

(a) REQUIREMENT.—Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to [substance abuse] *substance use disorder* education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b).

(b) PERMITTED DISCLOSURE.—

(1) CONSENT.—The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) METHOD FOR DISCLOSURE.—Whether or not the patient, with respect to whom any given record referred to in subsection (a) is maintained, gives written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report

of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(D) To a covered entity or to a program or activity described in subsection (a), for the purposes of treatment, payment, and health care operations, so long as such disclosure is made in accordance with HIPAA privacy regulation. Any redisclosure of information so disclosed may only be made in accordance with this section.

(E) To a public health authority, so long as such content does not include any individually identifiable health information and meets the standards established in section 164.514 of title 45, Code of Federal Regulations (or successor regulations) for creating de-identified information.

(3) DEFINITIONS.—For purposes of this subsection:

(A) COVERED ENTITY.—The term "covered entity" has the meaning given such term for purposes of HIPAA privacy regulation.

(B) HEALTH CARE OPERATIONS.—The term "health care operations" has the meaning given such term for purposes of HIPAA privacy regulation.

(C) HIPAA PRIVACY REGULATION.—The term "HIPAA privacy regulation" has the meaning given such term under section 1180(b)(3) of the Social Security Act.

(D) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term "individually identifiable health information" has the meaning given such term for purposes of HIPAA privacy regulation.

(E) PAYMENT.—The term "payment" has the meaning given such term for purposes of HIPAA privacy regulation.

(F) PUBLIC HEALTH AUTHORITY.—The term "public health authority" has the meaning given such term for purposes of HIPAA privacy regulation.

(G) TREATMENT.—The term "treatment" has the meaning given such term for purposes of HIPAA privacy regulation.

[(c) USE OF RECORDS IN CRIMINAL PROCEEDINGS.—Except as authorized by a court order granted under subsection (b)(2)(C), no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.**]**

(c) USE OF RECORDS IN CRIMINAL, CIVIL, OR ADMINISTRATIVE CONTEXTS.—Except as otherwise authorized by a court order under subsection (b)(2)(C) or by the consent of the patient, a record referred to in subsection (a) may not—

(1) be entered into evidence in any criminal prosecution or civil action before a Federal or State court;

(2) form part of the record for decision or otherwise be taken into account in any proceeding before a Federal agency;

(3) be used by any Federal, State, or local agency for a law enforcement purpose or to conduct any law enforcement investigation of a patient; or

(4) be used in any application for a warrant.

(d) APPLICATION.—The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when such individual ceases to be a patient.

(e) NONAPPLICABILITY.—The prohibitions of this section do not apply to any interchange of records—

(1) within the Uniformed Services or within those components of the Department of Veterans Affairs furnishing health care to veterans; or

(2) between such components and the Uniformed Services.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

[(f) PENALTIES.—Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with title 18, United States Code.]

(f) PENALTIES.—The provisions of sections 1176 and 1177 of the Social Security Act shall apply to a violation of this section to the extent and in the same manner as such provisions apply to a violation of part C of title XI of such Act. In applying the previous sentence—

(1) the reference to "this subsection" in subsection (a)(2) of such section 1176 shall be treated as a reference to "this subsection (including as applied pursuant to section 543(f) of the Public Health Service Act)"; and

(2) in subsection (b) of such section 1176—

(A) each reference to "a penalty imposed under subsection (a)" shall be treated as a reference to "a penalty imposed under subsection (a) (including as applied pursuant to section 543(f) of the Public Health Service Act)"; and

(B) each reference to "no damages obtained under subsection (d)" shall be treated as a reference to "no damages obtained under subsection (d) (including as applied pursuant to section 543(f) of the Public Health Service Act)".

(g) REGULATIONS.—Except as provided in subsection (h), the Secretary shall prescribe regulations to carry out the purposes of this section. Such regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) APPLICATION TO DEPARTMENT OF VETERANS AFFAIRS.—The Secretary of Veterans Affairs, acting through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Sec-

retary of Health and Human Services under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from [substance abuse] *substance use disorder*. In prescribing and implementing regulations pursuant to this subsection, the Secretary of Veterans Affairs shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

(i) ANTIDISCRIMINATION.—

(1) IN GENERAL.—No entity shall discriminate against an individual on the basis of information received by such entity pursuant to a disclosure made under subsection (b) in—

(A) admission or treatment for health care;

(B) hiring or terms of employment;

(C) the sale or rental of housing; or

(D) access to Federal, State, or local courts.

(2) RECIPIENTS OF FEDERAL FUNDS.—No recipient of Federal funds shall discriminate against an individual on the basis of information received by such recipient pursuant to a disclosure made under subsection (b) in affording access to the services provided with such funds.

(j) NOTIFICATION IN CASE OF BREACH.—

(1) APPLICATION OF HITECH NOTIFICATION OF BREACH PROVISIONS.—The provisions of section 13402 of the HITECH Act (42 U.S.C. 17932) shall apply to a program or activity described in subsection (a), in case of a breach of records described in subsection (a), to the same extent and in the same manner as such provisions apply to a covered entity in the case of a breach of unsecured protected health information.

(2) DEFINITIONS.—In this subsection, the terms "covered entity" and "unsecured protected health information" have the meanings given to such terms for purposes of such section 13402.

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DISSENTING VIEWS

H.R. 5795 could greatly harm efforts to combat the opioid epidemic. Confronting this tragic epidemic requires identifying strategies that promote more people with opioid use disorder (OUD) to enter and remain in treatment. Failure to do so leaves individuals and communities at increased risks of fatal and non-fatal overdoses, as people continue to seek out illicit opioids as part of their addiction. Unfortunately, H.R. 5795 increases the odds that fewer individuals with OUD enter and remain in treatment due to the weaker privacy protections afforded to a patient's substance use disorder (SUD) records under this bill.

Ensuring strong privacy protection is critical to maintaining individuals' trust in the health care system and willingness to obtain needed health services. These protections are especially important where very sensitive information is concerned. Information that may be contained in SUD treatment records is particularly sensitive because disclosure of SUD information has tangible vulnerabilities that are not the same as other medical conditions.

H.R. 5795 would dramatically reduce the privacy protection provided to individuals with SUD. Unlike current law, H.R. 5795 would allow a patient's SUD treatment records from Part 2 programs to be disclosed and redisclosed without patient consent for purposes of treatment, payment, and health care operations (TPO) by Part 2 programs and covered entities, including health care providers, health insurers, and health care clearinghouses. That means that such records can be shared between these health care organizations, even in instances when a patient objects to such disclosures out of concern that negative consequences could result.

By eliminating the patient consent requirement under 42 CFR Part 2 (Part 2) for TPO purposes, H.R. 5795 could result in individuals not seeking or remaining in treatment because they worry about the negative consequences that could result. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), those negative consequences can include loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration. Unlike other medical conditions, a person cannot be incarcerated for having a heart attack, legally fired for having cancer, or denied visitation with children due to severe acne.

Such concerns led patient and provider groups to submit testimony and letters to this Committee expressing grave concerns with this legislation. For example, the South Carolina Association of Opioid Dependence explained, "[e]ven with the growing awareness that substance use disorders are a disease, the unfortunate truth is that persons with a SUD are still actively discriminated against. This stigma and discrimination is heightened for individuals using Medication Assisted Treatments (MAT), such as treatment with

methadone and buprenorphine (best known as Suboxone), to address their OUD. Every day in South Carolina we see examples of discriminatory practices towards the persons we serve. Such as a patient getting dropped by his Primary Care Physician's office and cut off from needed medications for his medical conditions when the physician found out the patient is receiving methadone for an OUD. Or a baby being taken away from a new mother because she is on methadone for an OUD despite longstanding compliance with her treatment and abstinence from illegal drug-use." [1]

Another group, Raise the Bottom Addiction Treatment, one of two Medication Assisted Treatment facilities in Idaho, explained in expressing their opposition to this legislation "[o]ur patients come from every walk of life, including professionals and executives within our community. Their anonymity and privacy is of the utmost importance because their careers, families, and livelihood often depend on it. Knowing that people may seek treatment without fear of backlash and/or discrimination is often a deciding factor when considering entering treatment. To undo this protection will deeply affect one's ability and willingness to seek help. In Ada County alone, we suffered 8 deaths in the first 15 days of January due to overdose and suicide. Not only can the members of our community not afford to lose their right to confidentiality, but we as a nation cannot afford to move backwards in our fight to combat this opiate crisis." [2]

Recent headlines also present the serious risk faced by individuals with OUD when their disease status is disclosed. In a recent opinion piece in the New York Daily News by Dr. Jessica Gregg, an associate professor of medicine at Oregon Health and Science University, and medical director of the Oregon Health and Science University (OHSU) addiction medicine Extension for Community Health Care Outcomes (ECHO) clinic, she relayed the story of how a nursing facility decided that a patient's opioid addiction made her "too complicated" and refused to provide her care to recover from an infection.[3] In short, she wrote, quote: "in a health-care setting, the problem with stigma associated with drug addiction isn't just that it hurts people's feelings, or that it is shaming, or that it is unjust—though all of these things are true.[4] The problem with stigma is that patients with drug addiction get much, much worse care." [5]

These concerns are exacerbated because of the continuing occurrence of data breaches and privacy violations. A recent survey by the Ponemon Institute of health IT practitioners found that half of health care organizations governed by Health Insurance Portability and Accountability Act (HIPAA) lost or exposed patient data at

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[1] South Carolina Association for the Treatment of Opioid Dependence, *Letter to Chairman Greg Walden and Ranking Member Frank Pallone RE: Opposition to H.R. 3545—"Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care*, Apr. 17, 2018.

[2] Raise the Bottom Addiction Treatment, *Letter to Chairman Greg Walden and Ranking Member Frank Pallone RE: Opposition to H.R. 3545—"Overdose Prevention and Patient Safety Act" and Support for Other Legislative Proposals to Preserve Confidentiality and Coordinate Care*, May 17, 2018.

[3] New York Daily News, *The crippling stigma of drug addiction*, May 5, 2018, (http://www.nydailynews.com/opinion/crippling-stigma-drug-addiction-article-1.3971945?outputType=amp&_twitter_impression=true)

[4] *Id.*

[5] *Id.*

some point in the past year.[6] In addition, the Breach Barometer Report by Protenus found that 5.6 million patient records were exposed in 2017.[7] A recent prominent example of such disclosures was resolved a few months ago when Aetna agreed to pay millions of dollars to remedy privacy violations that revealed some of their members' HIV status to many unauthorized entities through the clear window of envelopes. As a recent commentary in Baker Hostetler's Data Privacy Monitor notes, "concern over data breaches often focus primarily on financial harms to the affected individuals, but the Aetna settlement serves as an important reminder that certain non-financial harms can be even more detrimental to those affected."[8] Members of the Aetna class action lawsuit reported damaged relationships with family or friends, loss of housing, extreme emotional distress and anxiety, and workplace issues.

While H.R. 5795 attempts to address the concerns about this legislation through the addition of provisions such as the antidiscrimination section that makes it illegal for lawful holders of these records to discriminate in certain ways based on such records, they are not enough. Such additions cannot compensate for the risk of stigma, discrimination, and negative health and life outcomes that could result from a roll back of Part 2's critical privacy protections. They also cannot compensate for the incomplete protection individuals with SUD are provided by federal civil rights statutes, such as the Fair Housing Act and the Americans with Disabilities Act. For example, individuals with SUD who are not in long-term recovery are not afforded all the protections provided by these laws.

Instead of increasing the uptake and retention of treatment by individuals with SUD, H.R. 5795 could erect a barrier to such individuals' willingness to take such action. As a result, H.R. 5795 could harm our efforts to respond to the opioid crisis. The stakes of taking any action that could result in any individual with an OUD, not seeking or remaining in treatment, should be rejected. As such, amid the worst opioid epidemic in U.S. history, I strongly oppose H.R. 5795 and believe it should be rejected.

Congress should heed the advice of the conferees that negotiated the confidentiality statute that first created Part 2. Those members stated: "The conferees wish to stress their conviction that the strictest adherence to . . . [confidentiality of substance use disorder patient records] is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his [or her] right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will attach for life will discourage thousands from seeking the treatment they must have if this tragic national problem is to be overcome." As the U.S. faces the current national drug abuse problem—the scale of which our country has never seen—

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[6] Politico Pro DataPoint on Health Care, *Survey, Half of HIPAA Organizations Lost or Exposed Data*, Mar. 21, 2018.

[7] Protenus, Inc., *Brach Barometer Report: Year in Review 5.6M Patient Records Breached in 2017, as Healthcare Struggles to Comprehensively and Proactively Detect Health Data Breaches*, 2017.

[8] Baker Hostetler Data Privacy Monitor, *Aetna Agrees to Pay $17 million and Implement Best-Practices Policy to Settle Claims of HIV-related Privacy Violations*, Jan. 25, 2018, (https://www.dataprivacymonitor.com/data-breaches/aetna-agrees-to-pay-17-million-and-implement-best-practices-policy-to-settle-claims-of-hiv-related-privacy-violations/).

maintaining the heightened privacy protections of Part 2 remains vital to ensuring all individuals with substance use disorder can seek treatment for their substance use disorder with confidence that their right to privacy will be protected.

FRANK PALLONE, Jr.,
Ranking Member.

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